FCA Defendants Should Consider 'Collateral Hope' Defense

By **Franklin Monsour Jr.** (September 16, 2022)


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Health care and life sciences companies are becoming more accustomed to the sharky waters of False Claims Act litigation.

The cases are usually initiated by a whistleblower's qui tam complaint alleging various ways defendants made false representations to the government in exchange for payment. Whether the government intervenes or not, the allegations are often too fact-intensive and intent-driven to be susceptible to dismissal.

Closer calls, even if ultimately meritless, can make it through summary judgment. And when that happens, similar to criminal prosecutions, too few of the cases go to trial. While someone's liberty is not at stake, the large sums sought and the threat of treble damages under the FCA are enough to motivate settlement.

The problem is compounded if the complaint is predicated on Anti-Kickback Statute violations, which, if proven, means a per se false claim. The result: In the last five years over 280 FCA cases settled, and it appears a whopping five went to trial.[1]

More defendants should fight these cases at trial.

One promising defense specific to the AKS is not new but remains largely untested. Let's call it the collateral hope defense. It dates back to U.S. v. McClatchey,[2] a criminal case in the U.S. Court of Appeals for the Tenth Circuit in 2000, which charged hospital executives with violating the AKS by compensating physicians in exchange for patient referrals.

There are many interesting facts about the case, not the least of which is that the district court set aside the jury's guilty verdict only to have the Tenth Circuit reverse the decision. But pertinent here is the jury instruction on the AKS charge that the Tenth Circuit upheld.

That instruction included the well-known one-purpose rule: that one is guilty of violating the AKS if only one motivating factor for paying remuneration was inducing referrals.

But it also included the qualification that a defendant "cannot be convicted merely because they hoped or expected or believed that referrals may ensue from remuneration that was designed wholly for other purposes."[3] Hence, the collateral hope defense.

Indeed, the court interpreted this instruction to mean remuneration is legal "so long as the hospital is motivated to enter into the relationship for legal reasons entirely distinct from its collateral hope for referrals."[4]

That's one tight distinction. The court noted that "it may be difficult for a jury to distinguish between a motivating factor and a collateral hope or expectation," before ultimately concluding that juries are supposed to make tough decisions.[5]

But tough jury calls are usually a problem for the plaintiff, who bears the burden of proof. While that burden was overcome in McClatchey — though in the circuitous way mentioned above — it has rarely, if ever, been tested in the numerous FCA cases that have recognized the collateral hope defense.[6]

In U.S. v. Regeneron Pharmaceuticals Inc. in the U.S. District Court for the District of Massachusetts,[7] for example, the FCA complaint alleged that defendant's drug copay assistance program was intended to induce prescribers to increase their prescriptions of a certain drug in violation of the AKS.

Concerning the issue of intent, the court stated that, while there was a reasonable interpretation of the facts that increased prescriptions were permissibly a collateral hope or expectation, ultimately "defendant's intent is a difficult factual determination that should be left for a jury to decide."[8] That case is still pending.

The case of U.S. v. Teva Pharmaceuticals USA Inc.[9] presented another common type of FCA claim — alleging the defendant violated the AKS by paying fees to prescribers for speaking engagements about certain drugs for the purpose of incentivizing prescriptions.

In discussing the intent requirement for inducing referrals, the court stated: "As the McClatchey court explained, a payor 'may lawfully enter into a business relationship with a doctor ... so long as [the payor] is motivated to enter the relationship for legal reasons entirely distinct from its collateral hope for referrals.'"[10]

The court noted that if the business arrangements appear above board, the jury may require greater evidence to find the defendant intended to induce referrals, as opposed to simply hoped for or expected them.[11] That greater evidence could include an actual quid pro quo, e.g., an explicit agreement for the defendant to receive referrals, which is not otherwise required to prove an AKS violation. In other words, the issue of intent becomes tougher for the plaintiff to prove.

So, what's evidence of an aboveboard arrangement look like?

The safe harbor regulations of the U.S. Department of Health and Human Services' Office of Inspector General provide guidance.[12] The term "safe harbor" has become somewhat of a misnomer: If the plaintiff proves remuneration was motivated by referrals, then the safe harbor does not apply. Thus, the safe harbor is really a road map for what type of evidence shows that remuneration was not motivated by referrals.

For example, any remuneration for health care provider services should be pursuant to a written agreement setting out job duties and hours required.[13] The remuneration should be for fair market value and not include the value of any referrals.[14] Those terms should be policed as an employer normally would, with agreements terminated for lack of performance.

A history of such terminations wouldn't be bad either. And having those decisions made or monitored by someone unconnected to revenue generation is a strong plus — something the HHS OIG has been requiring in corporate integrity agreements.

All of this begs the question: If the health care provider is paid pursuant to an aboveboard agreement unrelated to referrals, then why would the payor hope or expect the provider to refer business?

The answer presents a strong, commonsense argument. If the health care provider is speaking on behalf of, providing training for or helping develop the product, they presumably know about it and believe in it. And that assumption comes down to the payor's belief in its own product: Of course people who know about our product will recommend it!

There's lots of room to amp up evidence on that point, including data supporting the product, providers' happiness with the product and customer testimonials, all of which should be relevant to the defendant's intent: hope and expectation for referrals.

Case facts are never perfect. They're almost always open to interpretation. Good lawyering is needed. But if a defendant in an FCA complaint is facing allegations of AKS violations, they should weigh the facts supporting a collateral hope defense. If the facts are arguably there, plaintiffs should be forced to take on the difficult task of proving motivation over hope or expectation to a jury.

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[1] Figures are estimates based on a Lexis CourtLink list of False Claims Act cases between 2017 and 2022.

[2] United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000)

[3] Id. at 834.

[4] Id.

[5] Id. at 835 n.7.

[6] See, e.g., United States ex rel. Singh v. Bradford Reg. Med. Ctr., No. 04-186, 2007 U.S. Dist. LEXIS 39662 (W. Dist. Pa. May 31, 2007); United States ex rel. Ruscher v. Omnicare, Inc., 663 Fed. Appx. 368 (5th Cir. 2016); United States v. Teva Pharms. USA, Inc., No. 13 CIV 3702 (CM), 2019 U.S. Dist. LEXIS 35148 (S.D.N.Y. Feb. 27, 2019); United States v. Regeneron Pharms., Inc., No. CIV 20-11217-FDS, 2020 U.S. Dist. LEXIS 227643 (Dist. Mass. Dec. 4, 2020); United States v. Teva Pharms. USA, Inc., 560 F. Supp. 3d 412 (Dist. Mass. 2021).

[7] U.S. v. Regeneron Pharmaceuticals Inc., 2020 U.S. Dist. LEXIS 227643.

[8] Id. at 38-39.

[9] U.S. v. Teva Pharmaceuticals USA Inc., 2019 U.S. Dist. LEXIS 35148.

[10] Id. at 30 (alteration in original).

[11] Id. at 30-31.

[12] 42 CFR § 1001.952.

[13] Id. § 1001.952 (d).

[14] Id.